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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,391	01/08/2002	Eiji Shiojiri	215409US0	9970
22850	7590	11/22/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/926,391

**Applicant(s)**

SHIOJIRI ET AL.

**Examiner**

Chih-Min Kam

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-41 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,4,8-11,16-19,24-26,30-33 and 38-41 is/are rejected.  
7) ☒ Claim(s) 3,5-7,12-15,20-23 and 27-37 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed September 16, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

***Status of the Claims***

2. Claims 1 and 3-41 are pending.

Applicants' amendment filed September 16, 2004 is acknowledged. Applicant's response has been fully considered. Claims 1, 3-5 and 8-19 have been amended, claim 2 has been cancelled, and new claims 20-41 have been added. Therefore, claims 1 and 3-41 are examined.

**Objection Withdrawn**

3. The previous objection to the specification regarding new matter is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 17 in the amendment filed September 16, 2004.

**Rejection Withdrawn**

***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 1, 2 and 4-19 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 17 in the amendment filed September 16, 2004.
5. The previous rejection of claims 1-19 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claim, and applicant's response at pages 16-17 in the amendment filed September 16, 2004.

***Claim Rejections - 35 USC § 102***

6. The previous rejection of claims 1, 4, 8-11 and 16-19 under 35 U.S.C.102(b) as being anticipated by Saika *et al.* (WO/95/12611), is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 14-15 in the amendment filed September 16, 2004.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 24-26, 30-33 and 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Janecka *et al.* (J. Med. Chem. 38, 2922-2924 (1995)).

Janecka *et al* teach a series of reduced analogs of LHRH such as compound 29, AcDNal-Arg-DAlaNH<sub>2</sub>, and compound 31, AcDNal-DAlaNH<sub>2</sub>, which meet the structural criteria of the peptide of formula (1), for example, AcDNal-Arg-DAlaNH<sub>2</sub> corresponds to the tripeptide of

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formula (1), where Ar is 2-naphthyl, n is 1, X<sup>1</sup> is CH<sub>2</sub>, R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> are each H, R<sup>6</sup> is CH<sub>3</sub>CO-NH, R<sup>4</sup> is arginine side chain, X<sup>2</sup> is single bond, X<sup>3</sup> is NH, m is 1, R<sup>7</sup> is D-alanine side chain, R<sup>8</sup> is H, X<sup>4</sup> is NH, and R<sup>9</sup> is H (Table 1, compound 29; claims 24 and 25). Compounds 29 and 31 can be prepared with a pharmaceutically acceptable carrier such as HEPES buffer (page 2924, right column), which meet the criteria of claims 26, 30-33 and 38-41, because the compound contains the same structure as the claimed peptide of formula (I), thus it would be expected to have melanocyte-stimulating hormone inhibitory activity. Furthermore, the claim merely recites a whitening agent, an immunofunction controlling agent, an appetite controlling agent or a cosmetic preparation comprising the peptide of formula (I) as an active ingredient, and the compound 29 or 31 is an active ingredient in a composition for *in vitro* testing, therefore, claims 26, 30-33 and 38-41 are anticipated by the reference.

8. Claims 1, 4, 8-11 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Baudoin *et al.* (U. S. Patent 5,861,529, 102 (e) date, June 18, 1997).

Baudoin *et al* teach a series of substituted naphthoyl amino acid compounds having the formula (I) as transferase inhibitors, e.g., trifluoroacetate of N-[5-(2(R)-amino-3-mercaptopropionylamino)naphthyl-1-carbonyl]-L-methionine (columns 1-3; Example 1), which meet the structural criteria of the compound of formula (1), where n is 0, Ar-C(=O) is substituted naphthoyl (N-[5-(2(R)-amino-3-mercaptopropionylamino)naphthyl-1-carbonyl]), R<sup>2</sup> and R<sup>3</sup> are each H, R<sup>4</sup> is methionine side chain, X<sup>2</sup> is single bond, X<sup>3</sup> is O, m is 0 and R<sup>9</sup> is H (Example 1; claim 1). This compound and other substituted naphthoyl amino acids of formula (I) can be formulated with a pharmaceutically acceptable diluent or adjuvant (column 39, lines 24-40; Table 1), which meet the criteria of claims 4, 8-11 and 16-19, because this compound has the

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same structure as a compound of formula (1) of the claimed invention, thus it would be expected to have melanocyte-stimulating hormone inhibitory activity. Furthermore, the reference indicates the compound is prepared as an active ingredient of a composition for administration, and the claims merely recites a whitening agent, an immunofunction controlling agent, an appetite controlling agent or a cosmetic preparation comprising the peptide of formula (1) as active ingredient, therefore, claims 4, 8-11 and 16-19 are anticipated by the reference.

9. Claim 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Fukuda *et al.* (U. S. Patent 6,162,828, 102 (e) date, May 20, 1996).

Fukuda *et al* teach 1-Naphthylacetyl-Val-Ala-OH (column 42, line 25) and 2-Naphthylacetyl-Val-Ala-OH (column 42, line 60), which correspond the peptide of formula (1), where Ar is 1-naphthyl or 2-naphthyl, n is 1, X<sup>1</sup> is single bond, R<sup>1</sup>, R<sup>6</sup>, R<sup>2</sup> and R<sup>3</sup> are each H, R<sup>4</sup> is valine side chain, X<sup>2</sup> is single bond, X<sup>3</sup> is NH, m is 1, R<sup>7</sup> is alanine side chain, R<sup>8</sup> is H, X<sup>4</sup> is O, and R<sup>9</sup> is H (claim 24); and 1-Naphthoyl-Val-Ala-OH (column 43, line 27) and 2-Naphthoyl-Val-Ala-OH (column 43, line 63), which correspond to the compound of formula (1), where Ar is 1-naphthyl or 2-naphthyl, n is 0, R<sup>2</sup> and R<sup>3</sup> each is H, R<sup>4</sup> is valine side chain, X<sup>2</sup> is single bond, X<sup>3</sup> is NH, m is 1, R<sup>7</sup> is alanine side chain, R<sup>8</sup> is H, X<sup>4</sup> is O, and R<sup>9</sup> is H (claim 1).

### ***Claim Objections***

10. Claims 3, 5-7, 12-15, 20-23 and 27-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

11. Claims 1, 4, 8-11, 16-19, 24-26, 30-33 and 38-41 are rejected, and claims 3, 5-7, 12-15, 20-23 and 27-37 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



CMK  
November 17, 2004